

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 11

Remarks

Claims 1-45 were pending in the subject application. Applicants have hereinabove amended claims 20-21 and 33. Accordingly, claims 1-45 are now pending and presented for the Examiner's consideration.

Support for the amendments to claims 20-21 may be found inter alia in the specification, as originally-filed, on page 5, lines 8 to 15; page 6, lines 12 to 17; page 6, lines 23 to 27; page 11, lines 7 to 19; page 13, lines 10 to 20; page 63, line 18 to page 64, line 21; and page 114, line 8 to page 116, line 3.

Support for the amendments to claims 33 may be found inter alia in the specification, as originally-filed, on page 5, lines 8 to 15, page 6, lines 8 to 22; page 12, lines 1 to 10; page 65, lines 18 to 27; and page 66, line 15 to page 67, line 7, and page 72, lines 5 to 23.

Applicants maintain that the amendments to the claims raise no issue of new matter.

Restriction Requirement

In the February 9, 2004 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-X:

- I. Group I, claims 1-7, 13-15, 42, and 43, drawn to polynucleotides, nucleic acid molecular hybridization assays, and antisense agents, classified in class 536, Subclass 23.1 and 23.5 and class 435, subclass 6;
- II. Group II, claims 8-10, drawn to polypeptides, classified in class 530, Subclass 350;

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 12

- III. Group III, claims 11 and 12, drawn to antibodies, classified in class 530, Subclass 387.1;
- IV. Group IV, claims 16-19, drawn to methods of screening for neuroprotective compounds comprising no steps, classified in class unknown, subclass unknown;
- V. Group V, claims 20-26, drawn to methods for identifying a compound that inhibits or enhances the activity of a polypeptide, classified in class 536, Subclass 23.1 and 23.5 and class 435, subclass 6;
- VI. Group VI, claims 27 and 28, drawn to methods for preparing a composition containing a compound of undisclosed nature, classified in class unknown, subclass unknown;
- VII. Group VII, claims 29 and 33, drawn to methods of screening for compounds that induce or inhibit apoptosis, classified in class 435, subclass 4;
- VIII. Group VIII, claims 36 and 39, drawn to methods of identifying compounds by screening for polynucleotide expression, classified in class 435, subclass 6;
- IX. Group IX, claims 40 and 41, drawn to methods of identifying compounds that alter polypeptide activity, classified in class 436, subclass 86; and
- X. Group X, claims 44 and 45, drawn to methods of screening for up-regulating or down-regulating drugs comprising no steps, classified in class unknown, subclass unknown.

Claims 30-32, 34, 35, 37, and 38 were ungrouped because they are allegedly improper multiple dependent claims.

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 13

In the February 9, 2004 Office Action, the Examiner alleged that the polynucleotides and antisense agents of Group I are materially different from and are therefore, independent and distinct from the polypeptides of Group II and the antibodies of Group III. The Examiner alleged that the methods of each of Groups I and IV-X may be practiced independently of one another. The Examiner alleged that neither the polypeptides of Group II nor the antibodies of Group III are needed to practice the methods of Group I. The Examiner alleged that the polynucleotides and antisense agent of Group I have uses other than in the methods of Groups IV-X. The Examiner alleged that the polypeptides of Group II are materially different from and are therefore independent and distinct from the antibodies of Group III. The Examiner alleged that the polypeptides of Group II have uses other than in the methods of any one of Groups IV-X. The Examiner alleged that the antibodies of Group III have uses other than in the methods of any one of Groups IV-X. The Examiner alleged that the methods of each of Groups IV-X may be practiced independently of one another.

The Examiner alleged that claims 1-7, 13-17, 20-22, 29, and 43-45 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. The Examiner alleged that these claims are subject to restriction under 35 U.S.C. §121 as outlined in 1192 O.G. 68 (November 19, 1996); this notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

The Examiner further required that should Applicants elect a Group that claims or mentions more than one polynucleotide sequence, applicants are required to select no more than one of the individual sequences for examination. The Examiner alleged that the search of the no more than one selected sequence may

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 14

include the complement of the selected sequence and, where appropriate, may include e subsequences within the selected sequence.

The Examiner alleged that claims 8-12, 20-22, 33, 36, and 39-41 are drawn to large numbers of polypeptides or mention or require the use of large numbers of polypeptides. The Examiner required that should Applicants elect a Group that claims or mentions more than one polypeptide sequence, Applicants are required to elect one polypeptide sequence within the elected Group for examination on the merits.

The Examiner alleged that to search any two Groups as outlined above would create an undue burden for the USPTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

The Examiner alleged that because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated in proper.

In response, applicants hereby elect, with traverse, the invention of the 7 claims identified as Group V, specifically claims 20-26. Since Applicants have elected claims which refer to more than one polypeptide, Applicants elect the polypeptide encoded by the nucleic acid sequence shown in SEQ ID NO:94.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

The inventions of the cited Group I-X are not independent. Under

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 15

MPEP §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The claims of Group I-X are related in that they are drawn to similar compounds, compositions, and methods of use. The polypeptides of Group II and encoded by the polynucleotides of Group I. The antibodies of Group III recognize the polypeptides of Group II, which are encoded by the polynucleotides of Group I. All of the methods in Groups IV-X relate to screening for compounds which enhance, inhibit, or alter the expression or the polynucleotides of Group I or enhance, inhibit, or alter the activity of the polypeptides of Group II. The Applicants therefore maintain that the claims of these cited Groups are not "independent".

More specifically, Applicants respectfully request that the Examiner reconsider and include claims 39-41 with Group V for examination on the merits. Group V claims are drawn to methods for identifying a neuroprotective compound that *inhibits* or *enhances* the activity of a polypeptide. Claims 39-41 are drawn to methods of identifying neuroprotective compounds that *alter* the activity of a polypeptide. The activity of a polypeptide can only be "altered" by enhancement or inhibition. The Applicants therefore maintain that these claims are not "independent".

More specifically, Applicants respectfully request that the Examiner reconsider and include claims 33-35 with Group V for examination on the merits. Claims 33 is drawn to a method for identifying a compound that induces or inhibits apoptosis by testing the change in expression of a polypeptide. Claims 34-35 are drawn to methods for identifying a compound that induces or inhibits apoptosis by testing the change in activity of a polypeptide. Testing a change in expression of a polypeptide and testing a change in activity of a polypeptide are other ways of testing enhancement or inhibition of a polypeptide. The Applicants therefore maintain that these claims are not "independent".

Furthermore, under MPEP §803, there are two criteria for a proper

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 16

restriction requirement: 1) the invention must be independent or distinct (discussed above), and 2) there must be a serious burden on the Examiner if restriction is required. MPEP §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required between Groups I-X because a search for prior art material to the patentability of the claims of any of the Groups would necessarily turn up the prior art material to the patentability of the claims of any of the remaining Groups. Since there is no burden on the Examiner to examine Groups I-X together in the subject application, it is therefore submitted that the Examiner should examine the claims of Groups I-X on the merits.

More specifically, Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required between claims 20-26, 33-35, and 40-41 because a search for prior art material to the patentability of the claims would necessarily turn up the prior art material to the patentability of the other claims. All these pending claims recite methods for screening compounds by enhancing, inhibiting, or altering the expression or activity of a polypeptide. A search of prior art relating to methods of screening compounds utilizing a polypeptide will turn up prior art material to all the pending claims. Since there is no burden on the Examiner to examine claims 20-26, 33-35, and 40-41 together in the subject application, it is therefore submitted that the Examiner should examine all these claims on the merits.

SUMMARY

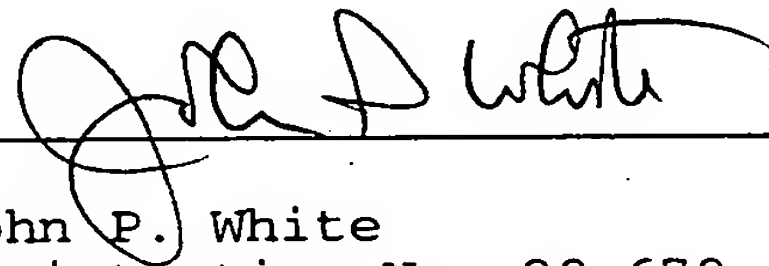
In view of the foregoing, applicants maintain that the February 9, 2004 restriction requirement is not proper under 35 U.S.C. §121 and respectfully request that the Examiner reconsider and withdraw the requirement.

Applicants: Elena Feinstein et al.
Serial No.: 10/021,338
Filed: December 12, 2001
Page 17

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



3/9/04

John P. White
Reg. No. 28,678

Date